AUG 3 0 2005

K051421

TAB 4

PREMARKET NOTIFICATION [510(K)] SUMMARY

October, 2004

Trade Name:	InterV brand V-Mark Breast Biopsy Site Marker with Titanium Anchor
Common Name:	Biopsy site markers
Classification Name:	Implantable stable (per 21 CFR section 878.4750)
Manufacturer's Name:	Medical Device Technologies, Inc. 3600 SW 47th Avenue Gainesville, FL 32608
Corresponding Official:	Kristine Liberacki Manager Regulatory Affairs and Quality Assurance 3600 SW 47th Avenue Gainesville, FL 32608 Phone: (800) 338-0440 ext 350 Fax: (352) 338-0662
Predicate Device(s):	Biopsy Sciences Biopsy Site Marker, K023694.
Device Description:	The V-Mark biopsy site marker is made of two components; a resorbable copolymer, a polyester derivative of lactic and glycolic acids, and a titanium anchor. Polylactic/polyglycolic acid copolymers degrade and resorb *in vivo* by hydrolysis into lactic and glycolic acids, which are then metabolized by the body. The titanium anchor provides a permanent component to the marker of the biopsy site. The site markers are deployed through an applicator that fits commercially available biopsy probes or coaxial needles including the J&J Ethicon Mammotome 11 gauge biopsy probe, the Pro-Mag Coaxial Introducer with Blunt Obturator, the Bio-Pince Co-axial Introducer with Blunt Obturator, and the Medical Device Technologies V-Core Co-axial Introducer. The V-Mark device marks the site of biopsy tissue sample, and is visible for up to 6 weeks by x-ray, ultrasound and MRI. The body then metabolizes the copolymer portion of the marker over time. The titanium anchor provides permanent radiographic visibility.

Intended Use:	To mark tissue during a percutaneous breast biopsy procedure, be visible under MRI and ultrasound for at least 6 weeks, and be permanently visible by fluoroscopy.
Technological Characteristics:	InterV brand V-Mark Breast Biopsy Site Markers are made of 75/25% poly(D,L-lactide-co-glycolide) copolymer into which a USP grade contrast agent has been incorporated to provide radiopacity, plus a titanium anchor that provides permanent radiopacity for marking the site of the breast biopsy. The markers are deployed into the biopsy needle tract using hand held instruments that are compatible with commercially available biopsy probes or coaxial needles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2005

Ms. Kristine Liberacki
Manager Regulatory Affairs and Quality Assurance
Medical Device Technologies, Inc.
3600 Southwest 47th Avenue
Gainesville, Florida 32608

Re: K051421
Trade/Device Name: Inter V® brand V-Mark™ Breast Biopsy Site Marker with Titanium Anchor
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: August 5, 2005
Received: August 12, 2005

Dear Ms. Liberacki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051421

TAB 3

INDICATIONS FOR USE

510(k) Number: _____

Device Name: InterV® brand V-Mark™ Breast Biopsy Site Marker with Titanium Anchor

Indications for Use:

The InterV brand V-Mark Breast Biopsy Site Marker with Titanium Anchor is intended to mark tissue during a percutaneous breast biopsy procedure, be visible under MRI and ultrasound for at least 6 weeks, and be permanently visible by fluoroscopy.

☒ **Prescription Use** (per 21 CFR 801 Subpart D) or ☐ **Over-The-Counter Use** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE)

Barbara Bucheit D for MKM

(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

3-**510(k)** Number K051421